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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/351,778	07/12/99	WOLD	W 16153-7775

HM12/0907

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EXAMINER	
WILSON,M	
ART UNIT	**PAPER NUMBER**
1633	8

DATE MAILED: 09/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/351,778	Applicant(s) Wold et al.
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-27* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-27* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Notice to Comply

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 10-15, 20-22, 24, drawn to a recombinant vector lacking E3 and methods of using thereof, classified in class 424, subclass 93.1.

II. Claims 1-3, 6, 7, 10, 11, 13, 14, 16, 17, 20-22, 24, drawn to recombinant vectors that are replication-restricted to neoplastic cells and methods of using thereof, classified in class 424, subclass 93.1.

III. Claims 1-3, 8-11, 13, 14, 18, 19-22, 24, drawn to recombinant vectors that comprise a tissue specific or inducible promoter substituted for the E4 region and methods of using thereof, classified in class 424, subclass 93.1.

IV. Claims 23, 25-27, drawn to a composition comprising a replication-defective adenovirus and a recombinant vector lacking E3, classified in class 424, subclass 93.1.

V. Claims 23, 25-27, drawn to a composition comprising a replication-defective adenovirus and a recombinant vector that is replication-restricted to neoplastic cells, classified in class 424, subclass 93.1.

VI. Claims 23, 25-27, drawn to a composition comprising a replication-defective adenovirus and a recombinant vector that comprises a tissue specific or inducible

promoter substituted for the E4 region recombinant vector, classified in class 424, subclass 93.1.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to different related but distinct products, restriction is deemed to be proper because these groups appear to constitute patentably distinct inventions for the following reasons:

Groups I and II are patentably distinct because they have different structures and different purposes. The vector of Group I is different than the vector of Group II because the vectors of Group I have wild-type E1 while the vectors of Group II have a deletion in E1. The vectors of Groups I and II have different replication patterns, different gene expression, different host cell ranges. Therefore, the vectors of Groups I and II have different functions and different effects. In addition, the vectors claimed in Group I include GZ1 and GZ3 which are 33.7 and 34.5 kb (SEQ ID NO:3 and 4) while the vectors in Group II include KD1 and KD3 which are 33.5 and 34.3 kb (SEQ ID NO:1 and 2). It would require an undue burden to search SEQ ID NO: 1-4. The vectors of Group I are not required for the vectors of Group II and vice versa. Therefore, the inventions are patentably distinct and separate.

Groups I and III are patentably distinct because they have different structures and different purposes. The vector of Group I is different than the vector of Group III because the vectors of

Group I have wild-type E1 while the vectors of Group III have a surfactant B promoter (SPB). The vectors of Groups I and III have different replication patterns, different gene expression, different host cell ranges. Therefore, the vectors of Groups I and III have different functions and different effects. In addition, the vectors claimed in Group I include GZ1 and GZ3 which are 33.7 and 34.5 kb (SEQ ID NO:3 and 4) while the vectors in Group III include KD1-SPB, KD3-SPB and dl01/07 which are 34.0, 34.7 and 36.1 kb (SEQ ID NO:14-16). It would require an undue burden to search SEQ ID NO: 3, 4 and 14-16. The vectors of Group I are not required for the vectors of Group II and vice versa. Therefore, the inventions are patentably distinct and separate.

Groups I and IV-VI are patentably distinct because they have different functions and different effects. The vector of Group I has a different function than the vector of Group I with a replication-defective adenovirus because the combination of both vectors is used to make viral particles (page 29). Thus, the vector of Group I can be used to kill cancer cells which is a different purpose that the combination of vectors to make viral particles. The vector of Group I is not required for the composition of Groups V and VI and vice versa. Therefore, the inventions are patentably distinct and separate.

Groups II and III are patentably distinct because they have different structures and different purposes. The vector of Group II is different than the vector of Group III because the vectors of Group II have a deletion in E1 while the vectors of Group III have a surfactant B promoter (SBF). The vectors of Groups II and III have different replication patterns, different gene expression, different host cell ranges. Therefore, the vectors of Groups II and III have

different functions and different effects. In addition, the vectors claimed in Group II include KD1 and KD3 which are 33.5 and 34.3 (SEQ ID NO:1 and 2) while the vectors in Group III include KD1-SPB, KD3-SPB and dl01/07 which are 34.0, 34.7 and 36.1 kb (SEQ ID NO:14-16). It would require an undue burden to search SEQ ID NO: 1, 2 and 14-16. The vectors of Group II are not required for the vectors of Group II and vice versa. Therefore, the inventions are patentably distinct and separate.

Groups II and IV-VI are patentably distinct because they have different functions and different effects. The vector of Group II has a different function than the vector of Group II with a replication-defective adenovirus because the combination of both vectors is used to make viral particles (page 29). Thus, the vector of Group II can be used to study adenoviral death protein which is a different purpose that the combination of vectors which is used to make viral particles. The vector of Group II is not required for the composition of Groups IV and VI and vice versa. Therefore, the inventions are patentably distinct and separate.

Groups III and IV-VI are patentably distinct because they have different functions and different effects. The vector of Group III has a different function than the vector of Group III with a replication-defective adenovirus because the combination of both vectors is used to make viral particles (page 29). Thus, the vector of Group III can be used to study adenoviral death protein which is a different purpose that the combination of vectors which is used to make viral particles. The vector of Group III is not required for the composition of Groups IV and V and vice versa. Therefore, the inventions are patentably distinct and separate.

Groups IV-VI are patentably distinct and separate inventions because viral particles made using the different combinations of vectors with replication-defective adenoviral vectors are used for different purposes. The composition of Group IV is used to make GZ1 and GZ3; the composition of group V is used to make KD1 and KD3 and the composition of Group VI is used to make KD1-SPB, KD3-SPB and dl01/07-SPB. The vectors produced each have different replication patterns, different gene expression, different host cell ranges. The vector of Group IV is different than the vector of Group V because the vectors of Group IV have wild-type E1 while the vectors of Group V have a deletion in E1. The vector of Group IV has wild-type E1 while the vectors of Group VI have a surfactant B promoter (SBF). The vector of Group V is different than the vector of Group VI because the vectors of Group V have a deletion in E1 while the vectors of Group VI have a surfactant B promoter (SBF). The combination of vectors in Group IV is not required for V or VI and vice versa and the combination of vectors in Group V is not required for V or VI and vice versa. Therefore, the compositions of Groups IV-VI are not disclosed as being used together.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Listing

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The sequences disclosed in the Tables on page 22 and 23 do not have sequence numbers.** Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." A complete response to the instant office action must include a complete and accurate response to the sequence listing requirements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120. The examiner can normally be reached on Monday through Friday from 8:30 am to 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. The fax phone number for this Group is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 305-0196.

Michael C. Wilson

Michael C. Wilson

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AU 1633

Application No.: 09/351778

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 18230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☒ 7. Other: The sequences disclosed on pages 22 & 23 do not have SEQ ID NOs.

Applicant Must Provide:

☒ An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
For PatentIn software help, call (703) 308-6856

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